NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

MELINTA THERAPEUTICS, LLC, et al.,

Plaintiffs,

v.

NEXUS PHARMACEUTICALS, INC.,

Defendant.

Case No. 2:21-cv-11198 (BRM) (AME)

OPINION

MARTINOTTI, DISTRICT JUDGE

Before this Court is Defendant Nexus Pharmaceuticals, Inc.'s ("Defendant") Motion to Dismiss Plaintiffs Melinta Therapeutics, LLC, Melinta Subsidiary Corp., and Rempex Pharmaceuticals, Inc.'s (collectively, "Plaintiffs") Complaint pursuant to Federal Rule of Civil Procedure 12(b)(3) and to Transfer Venue. (ECF No. 9.)¹ Plaintiffs opposed (ECF No. 12),² and Defendant replied (ECF No. 14). Having reviewed the parties' submissions filed in connection with the Motion and having declined to hold oral argument pursuant to Federal Rule of Civil Procedure 78(b), for the reasons set forth below and for good cause shown, Defendant's Motion to Dismiss and to Transfer Venue (ECF No. 9) is **GRANTED IN PART and DENIED IN PART**.

¹ On the eve of filing this decision, Defendant filed a motion to dismiss Count One. (ECF No. 35.) This decision moots that motion.

² Plaintiffs' Opposition Brief (ECF No. 12) corrected an earlier filed version (ECF No. 10).

I. BACKGROUND

A. Statutory Background

"[T]he regulatory scheme that governs the testing and approval of new drugs in the United States" was established by the Hatch-Waxman Act ("Hatch-Waxman"), 21 U.S.C. § 355. *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 143 (3d Cir. 2017). Under Hatch-Waxman, drug manufacturers seeking to market new prescription drugs must submit a New Drug Application ("NDA") to the Food and Drug Administration ("FDA") "and undergo a long, comprehensive, and costly testing process, after which, if successful, the manufacturer will receive marketing approval." *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 142 (2013) (citing 21 U.S.C. § 355(b)(1)). "In addition to extensive testing and safety information concerning the drug, the manufacturer must also submit the patent number and expiration date of any patent that claims the drug or a method of using the drug with respect to which a claim of patent infringement could reasonably be asserted." *Eisai Co. v. Mut. Pharm. Co.*, Civ. A. No. 06-3613, 2007 WL 4556958, at *1 (D.N.J. Dec. 20, 2007) (citing U.S.C. § 355(b)(1)). If an applicant's NDA is approved by the FDA, the patent information filed in connection with the NDA is published in the FDA's publication known as the "Orange Book." *Id.*

To further its goal of "increas[ing] competition between generic and brand-name drugs," Hatch-Waxman also "allows the manufacturers of generic drugs to obtain FDA approval without having to endure the gauntlet of procedures associated with NDAs." *In re Wellbutrin*, 868 F.3d at 143. Generic manufacturers may file an Abbreviated New Drug Application ("ANDA") "specifying that the generic has the 'same active ingredients as,' and is 'biologically equivalent' to, the already-approved brand-name drug." *Actavis*, 570 U.S. at 142 (quoting *Caraco Pharm*. *Lab'ys*, *Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012)). An ANDA allows a generic manufacturer to "avoid[] the 'costly and time-consuming studies' needed to obtain approval 'for a

pioneer drug," thereby furthering competition. *Id.* (quoting *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990)).

"In addition to streamlining the drug approval process, the Hatch-Waxman Act provides specialized procedures for brand-name and generic drug manufacturers to resolve intellectual property disputes." In re Wellbutrin, 868 F.3d at 144. Brand-name manufacturers are required to list in its NDA "the 'number and the expiration date' of any relevant patent." Actavis, 570 U.S. at 143 (quoting 21 U.S.C. § 355(b)(1)). Generic manufacturers, on the other hand, must assure their products will not infringe upon the brand-name's patents, which is known as a "paragraph IV notice." F.T.C. v. AbbVie, Inc., 976 F.3d 327, 339 (3d Cir. 2020); see also 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (certifying "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted"). After receiving a paragraph IV notice, a brand-name manufacturer has forty-five days to decide whether to sue the generic manufacturer for patent infringement. See 21 U.S.C. § 355(j)(5)(B)(iii). If it decides to sue within forty-five days, the brand-name manufacturer "is rewarded with some breathing space before competition can begin: the FDA is required to withhold approval of the generic drug for 30 months or until the infringement case is resolved, whichever comes first." In re Wellbutrin, 868 F.3d at 144 (citing 21 U.S.C. § 355(j)(5)(B)(iii)).

B. Factual Background

Plaintiffs are the owners of two patents, the '105 and '802 Patents, which describe and claim methods of treating bacterial infections. (ECF No. 1 ¶¶ 13–15.) The '105 and '802 Patents were listed in the FDA's Orange Book in connection with Plaintiffs' NDA for Minocin, a "100 mg/vial minocycline hydrochloride for injection" used "in the treatment of certain bacterial infections." (*Id.* ¶¶ 12, 16.) In December 2020, Defendant prepared an ANDA and sought FDA approval to manufacture and sell a generic version of Minocin before Plaintiffs' '105 and '802

Patents expired. (*Id.* ¶ 17.) Defendant also prepared a paragraph IV notice certifying the '105 and '802 Patents were "invalid, unenforceable, and/or [would] not be infringed by the" generic product. (*Id.* ¶ 18.)

According to Plaintiffs, on or around December 8, 2020, Defendant attempted to send Plaintiffs its paragraph IV notice through FedEx's "Priority Overnight" service. (*Id.* ¶ 19.) By this time, however, the COVID-19 pandemic had caused Plaintiffs to close their corporate offices to the public and implement a remote work policy. (*Id.* ¶ 20.) With these new policies in place, Plaintiffs established an internal, formal process for receiving and handling mail. (*Id.* (providing that "designated employees would timely open, review, and appropriately route electronic and hard copies of inbound correspondence").) Plaintiffs allege Defendant's paragraph IV notice did not go through this process and was only discovered by their general counsel on March 31, 2021. (*Id.* ¶ 21.) Moreover, Plaintiffs downloaded the FedEx package's tracking information, "which state[d] that the package was 'signed for' on December 8, 2020 by 'A. MELNTA.'" (*Id.* ¶ 22.) Upon review of Plaintiffs' records, however, there was no employee with such a name. (*Id.*)

C. Procedural Background

On May 13, 2021, within forty-five days of Plaintiffs' general counsel's March 31, 2021 discovery of Defendant's paragraph IV notice, Plaintiffs initiated the present matter. (*See generally id.*; *id.* ¶ 26.) Plaintiffs first assert the transmission of Defendant's paragraph IV notice "did not occur according to usual procedures, and there is no signature proof of delivery." (*Id.* ¶ 32; *see also id.* ¶ 33 (alleging that Defendant's "purported delivery" of its paragraph IV notice "was defective and did not result in [Plaintiffs] receiving the [n]otice").) Accordingly, in Count One, Plaintiffs seek declaratory judgment:

(1) that Defendant's attempted delivery of the Notice Letter on December 8, 2020, purporting to notify [Plaintiffs] that Defendant's ANDA contained a paragraph IV certification . . . did not commence the 45-day window for [Plaintiffs] to file suit to obtain a 30-month

stay of FDA approval of Defendant's ANDA...; (2) that Defendant must resend its Notice Letter and obtain proper confirmation of receipt by [Plaintiffs]; and (3) that the 45-day window will run only from the actual date of receipt by [Plaintiffs] following Defendant resending its Notice Letter; or, in the alternative (4) that the 45-day window began no earlier than March 31, 2021, when [Plaintiffs] first discovered the Notice Letter.

(*Id.* ¶ 1; see also id. ¶¶ 35–37.)

Additionally, "if this Court finds that Defendant is not required to resend the" paragraph IV notice, Plaintiffs set forth patent infringement claims. (Id. ¶ 2; see generally id. ¶¶ 38–61.) In Counts Two and Three of the Complaint, Plaintiffs allege Defendant had knowledge of the '105 and '802 Patents "prior to its ANDA submission and was aware that the filing . . . would constitute an act of infringement." (Id. ¶¶ 40, 52.) Moreover, Plaintiffs maintain Defendant's assertions in its paragraph IV notice "regarding [the] invalidity, unenforceability, and non-infringement of the" '105 and '802 Patents were "without merit and lack[ed] a good-faith basis." (*Id.* ¶¶ 46, 58.) Finally, Plaintiffs contend Defendant's generic product will (1) "have the same formulation and properties as Minocin," and (2) will use "a product label, prescribing information, and/or instructions for use that will substantially copy the Minocin label," thereby "induc[ing] physicians to treat bacterial infections in a manner within the scope of one or more claims of the" '105 and '802 Patents. (Id. ¶¶ 42–43, 54–55.) Because, according to Plaintiffs, "there are no substantial non-infringing uses of Defendant's ANDA [p]roduct" (id. ¶¶ 45, 57), Plaintiffs assert they are entitled to relief, "including an order of this Court that the effective date of the approval of Defendants' ANDA must be a date which is not earlier than the later of the expiration date of the ['105 and '802 Patents] or the expiration date of any exclusivity to which [Plaintiffs are] or become[] entitled." (Id. ¶¶ 47, 59.)

On July 1, 2021, Defendant filed the present Motion to Dismiss and to Transfer Venue. (ECF No. 9.) On July 19, 2021, Plaintiffs opposed. (ECF No. 12.) On July 26, 2021, Defendant replied. (ECF No. 14.)

II. LEGAL STANDARD

A. Rule 12(b)(3)

Rule 12(b)(3) permits the dismissal of a matter filed in an improper venue.

Venue in a patent infringement case is governed by 28 U.S.C. § 1400(b), which provides that "[a]ny civil action for patent infringement may be brought in the judicial district where the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business."

ES Distrib., LLC v. Hangtime LLC, Civ. A. No. 20-469, 2020 WL 6689755, at *1 (D.N.J. Nov. 13, 2020) (citing TC Heartland LLC v. Kraft Foods Grp. Brands LLC, 137 S. Ct. 1514, 1516–17 (2017)).

"The law of the Federal Circuit, rather than that of the Third Circuit, governs the Court's patent venue analysis under § 1400(b)," *Metuchen Pharms. LLC v. Empower Pharms. LLC*, Civ. A. No. 18-11406, 2018 WL 5669151, at *2 (D.N.J. Nov. 1, 2018), and provides, "upon motion by the [d]efendant challenging venue in a patent case, the [p]laintiff bears the burden of establishing proper venue." *In re ZTE (USA) Inc.*, 890 F.3d 1008, 1013 (Fed. Cir. 2018).

B. Transfer of Venue Pursuant to 28 U.S.C. § 1404(a)

"Section 1404(a) provides for the transfer of a case where both the original and the requested venue are proper." *Jumara v. State Farm Ins.*, 55 F.3d 873, 878 (3d Cir. 1995). The statute states: "For the convenience of the parties and witnesses, in the interest of justice, a district court may transfer any civil action to any other district or division where it might have been brought or to any district or division to which all parties have consented." 28 U.S.C. § 1404(a). When a plaintiff has laid a proper venue, "[t]he decision whether to transfer falls in the sound

discretion of the trial court." *Park Inn Int'l, L.L.C. v. Mody Enters., Inc.*, 105 F. Supp. 2d 370, 377 (D.N.J. 2000). "The burden of establishing the need for transfer . . . rests with the movant." *Jumara*, 55 F.3d at 879.

The Court must consider three factors when determining whether to grant a transfer under § 1404(a): (1) the convenience of the parties; (2) the convenience of the witnesses; and (3) the interests of justice. *Liggett Grp., Inc. v. R.J. Reynolds Tobacco Co.*, 102 F. Supp. 2d 518, 526 (D.N.J. 2000) (citing 28 U.S.C. § 1404(a)). These factors are not exclusive and must be applied through a "flexible and individualized analysis . . . made on the unique facts presented in each case." *Id.* at 527 (citations omitted). The first two factors have been refined into a non-exhaustive list of private and public interests that courts should consider. *See Jumara*, 55 F.3d at 879–80.

The private interests a court should consider include: (1) plaintiff's forum preference as manifested in the original choice; (2) the defendant's preference; (3) whether the claim arose elsewhere; (4) the convenience of the parties as indicated by their relative physical and financial condition; (5) the convenience of the witnesses; and (6) the location of books and records. *Danka Funding, L.L.C. v. Page, Scrantom, Sprouse, Tucker & Ford, P.C.*, 21 F. Supp. 2d 465, 474 (D.N.J. 1998) (citing *Jumara*, 55 F.3d at 879). The public interests a court should consider include: (1) the enforceability of the judgment; (2) practical considerations that could make the trial easy, expeditious, or inexpensive; (3) the relative administrative difficulty in the two fora resulting from court congestion; (4) the local interest in deciding local controversies at home; (5) the public policies of the fora; and (6) the familiarity of the trial judge with the applicable state law in diversity cases. *Id.* (citing *Jumara*, 55 F.3d at 879–80).

III. DECISION

A. Improper Venue

Defendant seeks dismissal of Plaintiffs' patent infringement counts, Counts Two and Three, for improper venue. (ECF No. 9-1 at 5–7.) First, Defendant notes it is incorporated in Illinois, not New Jersey, and, pursuant to § 1400(b), cannot be found to reside in New Jersey for patent venue purposes.³ (*Id.* at 6.) Second, Defendant maintains "Plaintiffs do not allege that any act involved in the preparation or submission of [Defendant's] ANDA . . . took place in New Jersey. Instead, Plaintiffs refer to another action altogether, which is that *after* [Defendant] submitted its ANDA, [Defendant] delivered a letter notifying Plaintiffs of the submission." (*Id.*) However, according to Defendant, venue inquiries related to ANDAs must "focus[] on the submission of the ANDA itself," not post-submission conduct. (*Id.* (citing *Valeant Pharms. N. Am. LLC v. Mylan Pharms., Inc.*, 978 F.3d 1374, 1381 (Fed. Cir. 2020) ("A plain language reading of this provision directs us to the conclusion that it is the submission of the ANDA, *and only the submission*, that constitutes an act of infringement in this context.")).) Accordingly, "[b]ecause Plaintiffs do not plead a legally sufficient basis for venue in this [D]istrict," Defendants argue Counts Two and Three should be dismissed. (*Id.*)

As set forth above, upon a defendant's venue challenge, a plaintiff in a patent infringement case bears the burden of establishing proper venue. *In re ZTE*, 890 F.3d at 1013. For their part, Plaintiffs concede "[t]here is no question" that venue choices in patent cases are limited. (ECF No. 12 at 12.) Moreover, Plaintiffs do not contest Defendant's Illinois corporate status nor assert Defendant maintains a regular and established place of business in New Jersey. (*See generally id.*) Rather, Plaintiffs argue "this case is a unique situation" in which the non-patent infringement

³ The Court agrees. "[F]or purposes of § 1400(b) a domestic corporation 'resides' only in its State of incorporation." *TC Heartland*, 137 S. Ct. at 1517.

claim, Count One, "is a necessary predicate to the patent infringement claims" of Counts Two and Three. (*Id.* at 12, 14; *see also id.* at 13 (asserting that "[a]llowing the strict post-*TC Heartland* venue rules for patent infringement lawsuits . . . to preclude this case from being heard in New Jersey puts the cart before the horse and . . . risks serious prejudice to Plaintiffs").) Accordingly, Plaintiffs request the Court exercise pendent venue over Counts Two and Three and allow the entire case to remain in this District. (*Id.* at 14.)

"Although venue must generally be established for each cause of action asserted in the complaint, there is an exception where claims arise out of the same operative facts." Neopart Transit, LLC v. Mgmt. Consulting, Inc., Civ. A. No. 16-3103, 2017 WL 714043, at *8 (E.D. Pa. Feb. 23, 2017) (internal quotation marks and citation omitted). "This doctrine, known as pendent venue, allows venue to be sustained over a federal claim even if venue over pendent state law claims would not be proper." Id.; see also Glenn v. Bair, Civ. A. No. 07-1691, 2007 WL 9789614, at *2 (D.N.J. Sept. 14, 2007) ("[T]he principle of pendent venue . . . provides that proper venue as to one claim will support adjudication of any other claim as long as the claims amount to a single cause of action." (quoting Archuleta v. Sullivan, 725 F. Supp. 602, 605-06 (D.D.C. 1989))). Courts, however, "have declined to invoke the pendent venue doctrine where a plaintiff brought both patent and non-patent claims and where § 1400(b) was not satisfied." Metuchen Pharms., 2018 WL 5669151, at *4 (collecting cases). Bio-Rad Laboratories, Inc. v. 10X Genomics, Inc., Civ. A. No. 19-12533, 2020 WL 2079422 (D. Mass. Apr. 30, 2020), the sole case Plaintiffs cite in support of pendent venue (ECF No. 12 at 13–14), echoes this position. 2020 WL 2079422, at *9 ("Other courts have determined that the doctrine of pendent venue does not extend to patent claims.").

Importantly, *Bio-Rad* is plainly distinguishable from the present matter. *Bio-Rad* involved allegations of infringement on three patents, two of which were subject to a forum selection clause

requiring litigation take place in the District of Massachusetts. Id. at *1–2. The court found pendent venue proper for the third patent, which was not subject to the forum selection clause, holding "[t]he other cases which have refused to allow pendent venue involved plaintiffs who brought nonpatent claims and sought to use pendent venue to skirt section 1400's requirements for the patent claims." Id. at *9 (collecting cases). In other words, the court determined because the plaintiffs' properly venued claims were patent claims, exercising pendent venue was appropriate. *Id.* ("This is not the case here. The primary claims are patent claims and are properly venued, thus this Court can exercise pendent venue over the [third] patent."); see also ARP Wave, LLC v. Salpeter, 364 F. Supp. 3d 990, 997 (D. Minn. 2019) ("Every court that has addressed the issue following TC Heartland . . . has found that there is no 'pendent' venue over a patent-infringement claim unless there is 'original' venue over a separate patent-infringement claim under § 1400(b)."). Here, however, Plaintiffs' primary, properly venued claim is not a patent claim, but rather one seeking declaratory judgment.⁴ (See ECF No. 1 ¶¶ 27–37.) The Court, therefore, follows the courts from within and outside this District and declines to exercise pendent venue over Counts Two and Three. See Metuchen Pharms., 2018 WL 5669151, at *4; see also Akurate Dynamics, LLC v. Carlisle Fluid Techs., Inc., Civ. A. No. 20-606, 2021 WL 860006, at *2 (W.D. Tex. Mar. 8, 2021) ("[I]n accordance with TC Heartland, this [c]ourt holds that § 1400(b) is the sole and exclusive provision controlling venue in patent infringement cases; pendent venue does not apply in this case."); Evans v. Bearback, LLC, Civ. A. No. 20-172, 2020 WL 8366982, at *2 (N.D. Fla. Nov. 6, 2020) ("Moreover, the [c]ourt would decline to exercise pendent venue over the patent infringement claims in any event because doing so would override the clear legislative policy embodied in

⁴ While Count One does relate to Hatch-Waxman and patent infringement, it is not, in fact, a patent infringement claim.

§ 1400(b)."); *High 5 Games, LLC v. Marks*, Civ. A. No. 13-7161, 2019 WL 3761114, at *9 n.10 (D.N.J. Aug. 9, 2019) (noting that, in light of *Metuchen Pharmacies*, plaintiff withdrew its pendent venue argument). Having determined Plaintiffs do not assert venue is proper under § 1400(b),⁵ the Court finds Plaintiffs have failed to meet their burden of demonstrating proper venue.

Outright dismissal of Counts Two and Three, however, would be a "harsh remedy." *ES Distrib.*, 2020 WL 6689755, at *3 (quoting *NCR Credit Corp. v. Ye Seekers Horizon, Inc.*, 17 F. Supp. 2d 317, 319 (D.N.J. 1998)). For cases filed in an improper venue, a district court may, in the interest of justice, *sua sponte* "transfer such case to any district or division in which it could have been brought." 28 U.S.C. § 1406(a); *Decker v. Dyson*, 165 F. App'x 951, 954 n.3 (3d Cir. 2006). Accordingly, to the extent Defendant seeks dismissal of Counts Two and Three, Defendant's Motion is **DENIED**. However, because Defendant is incorporated in Illinois, and because patent infringement suits may be brought in the district of incorporation, *see* 28 U.S.C. § 1400(b); *TC Heartland*, 137 S. Ct. 1517, the Court will **TRANSFER** Counts Two and Three to the Northern District of Illinois, the appropriate venue for this matter.⁶

B. Transfer

Defendant also seeks to transfer Count One of Plaintiffs' Complaint to the Northern District of Illinois. (ECF No. 9-1 at 7–9.) Pursuant to 28 U.S.C. § 1404(a), "[f]or the convenience of parties and witnesses, in the interest of justice, a district court may transfer any civil action to any other district or division where it might have been brought." In addition to § 1404(a)'s enumerated interests, courts should also review the following private interests:

⁵ That is, Plaintiffs do not assert (*see generally* ECF No. 12) Defendant is incorporated or maintains a regular and established place of business, or committed acts of infringement, in New Jersey. *See* 28 U.S.C. § 1400(b).

⁶ In its Moving Brief, Defendant asserts it "is located within the Northern District of Illinois, and submitted the ANDA from there as well." (ECF No. 9-1 at 8.)

plaintiff's forum preference as manifested in the original choice; the defendant's preference; whether the claim arose elsewhere; the convenience of the parties as indicated by their relative physical and financial condition; the convenience of the witnesses—but only to the extent that the witnesses may actually be unavailable for trial in one of the fora; and the location of books and records (similarly limited to the extent that the files could not be produced in the alternative forum).

Jumara, 55 F.3d at 878 (internal citations omitted) Courts should also consider the following public interests:

the enforceability of the judgment; practical considerations that could make the trial easy, expeditious, or inexpensive; the relative administrative difficulty in the two fora resulting from court congestion; the local interest in deciding local controversies at home; the public policies of the fora; and the familiarity of the trial judge with the applicable state law in diversity cases.

Id. (internal citations omitted).

Here, the Court finds *Metuchen Pharmaceuticals* to be instructive. There, having determined the District of New Jersey was not a proper venue for the plaintiffs' patent claim, the court transferred the matter—including the non-patent state law claims—to the Southern District of Texas. *Metuchen Pharms.*, 2018 WL 5669151, at *4–6. The court first "acknowledge[d] that [p]laintiffs ha[d] manifested a clear preference for" the District of New Jersey, that the District would be a convenient forum for the New Jersey-based plaintiff, and that the court's "familiarity with New Jersey law weigh[ed] in favor of adjudicating [p]laintiffs' state law claims in" New Jersey rather than Texas. *Id.* at *5. However, the court went on to hold the "[d]efendants, as well as relevant evidence, [were] located in Texas," and that the plaintiffs' "non-patent claims [arose] from the same underlying set of facts as" the improperly venued patent claim. *Id.* Moreover, the court determined "dismissing or transferring [p]laintiffs' patent claim," which could not "properly proceed" in the District of New Jersey, "and allowing [p]laintiffs' non-patent claims to proceed in [the] District would result in two nearly identical trials in different courts, which would greatly

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inconvenience the parties and the witnesses, as well as unnecessarily burden the courts with

duplicative litigation." Id. Here, the Court finds no reason to deviate from this sound reasoning.

Defendant—as well as the evidence relevant to the ANDA and paragraph IV notice shipment—is

located in Illinois, and judicial economy suggests this Court should not continue to entertain a

request for declaratory judgment so closely intertwined with the soon-to-be-transferred patent

claims. Therefore, pursuant to § 1404(a), Count One of Plaintiffs' Complaint is **TRANSFERRED**

to the Northern District of Illinois.

IV. **CONCLUSION**

For the reasons set forth above, Defendant's Motion to Dismiss and to Transfer Venue

(ECF No. 9) is **GRANTED IN PART and DENIED IN PART**. Defendant's Motion to Dismiss

Count One (ECF No. 35) is moot. An appropriate order follows.

Date: November 5, 2021

/s/ Brian R. Martinotti

HON. BRIAN R. MARTINOTTI UNITED STATES DISTRICT JUDGE

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